

Patent claims:

1. A process for detecting or determining a C-peptide-containing impurity in a sample of recombinantly produced human insulin or a derivative thereof, by a non-radioactive assay, comprising the steps:
 - 5 (a) preparing a sample of recombinantly produced human insulin or a derivative thereof;
 - (b) mixing the samples with dilution buffer;
 - (c) adding a tracer to mixture (b);
 - (d) adding antibody specific for the C-peptide impurity to mixture (c);
 - 10 (e) adding "C-peptide second antibody bead" having at least one label to mixture (d); and
 - (f) detecting or determining the presence of the C-peptide-containing impurity.
- 15 2. The process according to claim 1, wherein the C-peptide-containing impurity is C-peptide, preproinsulin or a derivative thereof, or a C-peptide containing insulin or a derivative thereof.
3. The process according to claim 1, wherein the process is performed at a pH of
20 about 8.5 to about 9.0.
4. The process according to claim 1, wherein the antibody specific for the C-peptide recognizes monkey C-peptide.
- 25 5. The process of claim 1, wherein the antibody is chosen from:
Z2127, 99Ser1_SD2/F17-22;
Z94, 99Ser2_SD2/P3;
S95-11, 99Ser7/SD2-650/F17-22;
S95-11, 99Ser8/SD2-651/F17-21;
30 S95-11, 99Ser9/SD2-652/F17-24;
S95-11, 99Ser10/SD2-680/F15-25;
S95-11, 99Ser11/SD2-681/F15-24; or
S95-11, 99Ser12/SD2-682/F15-24.